# Appendix A HMPTS Quality Assurance Terms, Definitions, and Concepts

#### 1.0 Overview

DOE Order 5700.6C Quality Assurance states that a vocabulary that is consistent with and representative of the particular site and operation is to be defined and adopted. This section defines some of the QA terms and concepts used in carrying out the quality assurance functions in HMPTS. It is also designed to enhance the communication between HMPTS members and non-members by clearly defining the site and operation specific vocabulary used.

## 2.0 LLNL HMPTS QA Terms, Definitions, and Concepts

**Assessment/Verification** — The act of reviewing, inspecting, testing, checking, conducting surveillance, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in DOE 5700.6C, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.

**Carrier** — Any person engaged in the transportation of passengers or property as common, contract, or private charter, or freight forwarder, as those terms are used in the Interstate Commerce Act, as amended, or by the U.S. Postal Service.

**Category** — There are three categories of hazardous material in the HMPTS Program.

**Category I** – All hazardous materials, defined in 49 CFR 171.8, that are also designated "Controlled Materials". (This includes, but is not limited to, hazardous classified material, non-waste quantities of fissionable and other radioactive materials and explosives, nuclear components and special assemblies).

**Category II** – All unclassified hazardous materials of negligible economic value; i.e., hazardous and radioactive wastes.

**Category III** – All hazardous materials other than those in Category I or II.

**Certificate of Conformance/Compliance** — A document signed or otherwise authenticated by an authorized individual certifying the degree to which an item, system, or activity meets specified requirements of the relevant specification, contract, or regulation.

**Controlled Material** — Any material that is designated by the DOE or LLNL for special control because it is classified, hazardous, of national interest, or valuable.

**Corrective Action** — Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

**Finding** — A noncompliance of importance which may affect the program or ES&H, or a noncompliance that indicates the need for prompt corrective action normally identified as a result of an internal or independent assessment. Findings require corrective action.

#### Hazardous Materials, Hazardous Substances, and Hazardous Waste —

**Hazardous Material** – A substance or material including hazardous substance, which has been determined by the Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which has been so designated. (Defined by the DOT Hazardous Material Regulations, 49 CFR 171.8).

**Hazardous Substances** – A material, including its mixtures and solution that are listed in the appendix to section 172.101 of 49 CFR, in a quantity, in one package which equals or exceeds the reportable quantity (RQ) listed in the appendix to section 172.101. (For a more detailed definition, see section 171.8 of 49 CFR).

**Hazardous Waste** – All nonradioactive material that is subject to Hazardous Waste Manifest Requirements of the EPA regulations specified in 40 CFR Parts115, 116 and 262.

**Inspection** — Activities, such as examining, measuring, testing, or gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity.

**Item** — An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts or data.

**Nonconformance** — A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

**Observation** — An item of objective evidence found during an audit.

**Offsite** — For hazardous materials packaging and transportation activities, or hazardous waste generation, "offsite" is any activity performed outside of the geographically contiguous private property owned by or under the control of LLNL.

**Onsite** — For hazardous materials packaging and transportation activities, or hazardous waste generation, "onsite" is any activity performed within the geographically contiguous private property owned by or under the control of LLNL.

**Organizational Authority** — Authority that is defined by virtue of an individual's position on the organizational chart.

**Package** — A packaging plus its contents as presented for transport.

**Packaging** — The assembly of one or more containers and any other components attached thereto, including inner receptacles, absorbent materials, supporting structures, thermal insulation, and supplementary attached equipment, necessary to assure compliance with the minimum packaging requirements. (See Section 171.8 of 49 CFR for more details).

### For Radioactive Materials, the Packaging Definition is:

One or more receptacles and wrappers and their contents excluding fissile material and other radioactive material, but including absorbent material, spacing structures, thermal insulation, radiation shielding, devices for cooling and for absorbing mechanical shock, external fittings, neutron moderators, non fissile neutron absorbers, and other supplementary equipment.

**Type A Packaging** – A packaging designed to retain specified integrity of containment and shielding of radioactive material under prescribed normal conditions of transport. See 49 CFR 173.411, 173.412, 173.461, 173.465, 173.466, DOE Order 5480.3 and DOE Order 1540.2; or a DOT specification package certified as Type A in the Mound DOT Spec. 7A Document, MLM 3245.

**Type B Packaging** – A packaging designed to retain specified integrity of containment and shielding of radioactive material when subjected to the prescribed normal conditions of transport and to the hypothetical accident test conditions. See 49 CFR 173.403, 173.467, 10 CFR 71, DOE Order 5480.3 and DOE Order 1540.2.

**"Strong Tight"** – A package that will not leak radioactive materials during conditions normally incident to transportation which is used for the shipment of low specific activity radioactive material and other uses. See 49 CFR 173.421 and 173.425.

**Prescriptive Application of QA** — An approach to QA that imposes excessive controls that are disproportionate to and incommensurate with the scale, cost, complexity, hazards, and programmatic significance of an activity. The prescriptive application of QA is not value-added.

**Quality** — The degree to which an item or process meets or exceeds the user's requirements and expectations.

**Quality Assurance** — Actions that provide confidence that quality is achieved. A system of administrative and technical checks and balances initiated to ensure the specified requirements are met. The term includes other related terms such as "quality control" and "compliance inspection."

**Quality Assurance Program** — The overall program established by an organization to implement the requirements of the contract, order or regulation. The Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.

**Quality Record** — Documented evidence of the quality of items and/or activities affecting quality.

**Radioactive Material** — Any material having activity greater than 0.002 microcuries per gram ( $\mu$ Ci/g) as defined by 49 CFR 173.403 (y).

**Type A Quantity** – The maximum number of curies of special form (A1) or normal form (A2) of a given radionuclide permitted in a Type A package.

**Type B Quantity** – Any quantity greater than A1 or A2 which must, therefore, be shipped in a Type B Container.

**Fissile Material** – Any material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium-238, -239, -241, and uranium-233, -235, neptunium-237, and curium-244.

**Low Specific Activity (LSA) Material** – Material of low radioactivity level such as ores and chemical concentrations of those ores. See 49 CFR 173.403 for detail definition.

**Limited Quantity of Radioactive Material** – A quantity of radioactive material not exceeding the materials package limits specified in 49 CFR 173.423 and which conform with requirements specified in 173.421.

**Record copy** — The office which is responsible (custodian) for insuring that a record meets its retention requirements, officially stores and maintains the "record copy" of that record. For example, the Procurement Department is responsible for the "record copy" of purchase orders. All other copies are considered to be "non-record" or reference only copies.

**Repair** — The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though the item still does not conform to the original requirements.

**Rework** — The process by which an item is made to conform to the original requirements by completion or correction.

**Specific Quality Assurance Plans** — The Specific Quality Assurance Plans are the policies, implementing documents and procedures that meet the requirements of HMPTS QAP and are used in the day-to-day work involved in meeting HMPTS organizational performance objectives by the Committee Divisions and Sections.

**Substance over Format** — An approach to evaluating the adequacy of the implementation of QA policy in which the adequacy of the management controls described is the primary criterion of evaluation not the specific format of the implementation plan.

**Supplier** — General term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and can apply to sub-tier levels as well.

**Transportation** — The on-site or off-site activity of moving cargo from one point to another utilizing a transport vehicle. Transport can refer to on-site transfer or off-site shipment of hazardous materials, substances, or wastes.

**Testing** — The determination of the capability of an item or process to meet specified requirements by subjecting it to a set of physical, chemical, environmental, or operating conditions.

**Transfer** — The on-site movement of hazardous materials, hazardous substances, or hazardous waste as well as other material within LLNL site boundaries.

**Value-Added** — Any action or policy that improves the performance of a product or service and/or increases its cost-effectiveness and if removed would exert a negative causal effect on the performance or cost effectiveness of the product or service.

**Work** — Process of performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

#### **HMPTS QAP – ACRONYMS**

AD Associate Director for Plant Operations at LLNL

ANSI American National Standards Institute

ASME American Society of Mechanical Engineers

ASTM American Society for Testing Materials

CFR Code of Federal Regulations

CMO Certification Management Officer

DOE Department of Energy

DOE MD Department of Energy Management Directive

DOHS Department of Health Services – California

DOT Department of Transportation

ES&H Environment, Safety, and Health

EPA Environmental Protection Agency

FSP Facility Safety Procedure

GRS General Records Schedule

HCD Hazards Control Department

HMPTS Hazardous Material Packaging and Transportation Safety

HWM Hazardous Waste Management

IAEA International Atomic Energy Agency

IATA International Air Transportation Association

ICAO International Civil Aviation Organizatio

IMDG International Maritime Dangerous Goods

IMO International Maritime Organization

LLNL Lawrence Livermore National Laboratory

LLW Low Level Waste

MDD Material Distribution Division

MMS Material Management Section

MTE Measuring and Test Equipment (also M&TE)

NCR Non Conformance Report

NRC Nuclear Regulatory Commission

OSP Operational Safety Procedure

P&T Packaging and Transportation

PO Purchase Order

SDD Supply and Distribution Department

SARP Safety Analysis Report for Packaging

SF DOE San Francisco Operations Office (formerly SAN)

SQAP Specific Quality Assurance Plan

QA Quality Assurance

QC Quality Control

QAP Quality Assurance Plan

TRU Transuranic

WAA Waste Accumulation Area